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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/463,276	05/12/00	FIRST N	96429/9085

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TERESA J WELCH
MICHAEL BEST & FRIEDRICH
ONE SOUTH PINCKNEY STREET SUITE 700
PO BOX 1806
MADISON WI 53701-1806

EXAMINER	
WOITACH, J	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 10/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Offic Action Summary	Application No. 09/463,276	Applicant(s) FIRST ET AL.	
	Examiner Joseph Woitach	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-15 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-15 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This application filed May 12, 2000, is a 371 national stage filing of PCT/US98/15387, filed July 24, 1998.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: The correction to the name of Maissam Mitalipova are not initialed and dated.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 12, 14 and 15 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are directed to 'and embryo'. As written, the claims read on cells that are a human embryo. A human being or human embryo is not-statutory subject matter. See 1077 O.G. 24, April 21, 1987. Amending the claim to recite a non-human embryo would obviate the basis of the rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:

In claim 5, the recitation of "the group of bovine oocytes" is unclear because claim 4 only recites a bovine oocyte, and it is not clear to from or to what the oocytes belong.

Claim 6 is unclear in the recitation of 'said enucleated bovine recipient oocyte' because a bovine is not recited in claim 1. Though a bovine could represent a species of oocyte there is insufficient antecedent basis in claim 1 for the recitation of bovine.

Claim 8 is unclear in the recitation 'and the incubating with serine kinase inhibitor' because it is not clear to what the incubating is referring. Amending the claim to 'and --then–' would obviate the rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12, 14 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Barnes *et al.* (Molecular Reproduction and Development, 1992 IDS reference).

Claims 12, 14 and 15 are directed to an embryo produced by the method of claim 1 or claim 13. It should be noted that the patentability of a product-by-process claim is determined by the novelty and nonobviousness of the claimed product itself without consideration of the process for making it which is recited in the claims. *In re Thorpe*, 227 USPQ 964 (Fed. Cir. 1985). This is because the final product (the embryonic or stem-like cells) is not distinguished by any particular features or characteristics as a result of the process by which it is made. As such, the limitations of the claimed cells are met by any embryo taught in the prior art. Barnes *et al.* teach the isolation and *in vitro* culturing of bovine embryos.

Accordingly, Barnes *et al.* clearly anticipate claims 12, 14 and 15.

Claims 12, 14 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Gurdon (J. Cell. Sci., 1986 IDS reference).

Claims 12, 14 and 15 are directed to an embryo produced by the method of claim 1 or claim 13. It should be noted that the patentability of a product-by-process claim is determined by the novelty and nonobviousness of the claimed product itself without consideration of the process for making it which is recited in the claims. *In re Thorpe*, 227 USPQ 964 (Fed. Cir. 1985). This

is because the final product (the embryonic or stem-like cells) is not distinguished by any particular features or characteristics as a result of the process by which it is made. As such, the limitations of the claimed cells are met by any embryo taught in the prior art. Gurdon teaches nuclear transfer between different species. In particular, Gurdun reviews the development of hybrid nuclear transplant embryos (page 302; summarized in figure 6).

Accordingly, Gurdun anticipates claims 12, 14 and 15.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prather *et al.* (Biology of Reproduction, 1987, IDS reference), Gurdon (J. Cell. Sci. , 1986), Campbell *et al.* (WO 97/07668, March 1997, IDS reference), Telford *et al.* (Molecular Reproduction and

Development, 1990, IDS reference) and Dominko *et al.* (Molecular Reproduction and Development, 1997, IDS reference).

Claims 12, 14 and 15 are summarized above. Claims 1-11 and 13 are drawn to a method of producing nuclear transfer embryos from donor cell of one species and recipient oocytes from another species comprising: inducing the donor cell to undergo Go arrest; fusing said donor cell to an enucleate recipient; and activating said nuclear transfer unit. Dependent claims recite that the Go arrest be induced by low serum, and that the fusion be performed 16-32 hours after *in vitro* culturing. Prather *et al.* and Gurdon teach methods of trans species nuclear transfer, wherein the nuclei from a donor of one species is transplanted into an enucleated oocyte recipient of a second different species (summarized in each of the abstracts). It is noted by Gurdon that transpecies nuclear transfer has been attempted for a wide variety of species of animals, however it is observed that the distance in the species/taxinomic relationship of the donor and recipient is correlated with developmental abnormalities and arresting of embryogenesis in the chimeric embryo (results summarized in Figure 6). The instant claims are not restricted to producing an embryo capable of completing embryogenesis or a viable fetus, and thus, the experiments described by Prather *et al.* and Gurdon provide the evidence that transpecies nuclear transfer techniques have been practiced prior to the time of the claimed. Both Prather *et al.* and Gurdon teach the transpecies nuclear transfer is possible, however optimization of conditions would be necessary to produce a chimeric embryo capable of longer term culturing or capable of progressing through embryogenesis (Gordon-pages 310-312 and Prather-page 865; end of

discussion section). Campbell *et al.* provides a more recent status of nuclear transfer techniques. In particular, Campbell teaches the use of donor cells which have been arrested in Go by various methods, maturation curves of the bovine oocyte, and activation of the NT unit by various techniques known in the art. Further, Campbell teaches that the described nuclear transfer technology can be used to generate transgenic animals as well (entire reference; summarized in abstract and specifically claimed). Dominko *et al.* and Telford *et al.* both provide further guidance for the optimization of in using bovine oocytes. Specifically, Dominko *et al.* demonstrate that there is an increased efficiency in embryo development when the genetic material is transferred later that 8 hours of culturing (Figures 3 and 4). Telford *et al.* teach that there is a transition from maternal control (donor oocyte control) to the embryo for various species of animals (page 93; summarized in Table 1). In particular, in the cow, this change occurs between 8-16 hours. In view of the work of Dominko *et al.* and Telford *et al.*, it is clear that to establish the control of the genetic material transferred by nuclear transfer techniques, at least in the bovine, the artisan would deliver the nuclei after the 16 hour culture transition period. Therefore, in view of the art as a whole, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to generate chimeric embryos by nuclear transfer techniques. As noted above, cross-species nuclear transfer has been performed for prior to the time of the claimed invention, however it was also observed that optimization of the methods wold be necessary. Campbell *et al.*, Telford *et al.* and Dominko *et al.* provide such optimization conditions detailing specific method steps and materials necessary to increase embryo

development for the cow. One of skill in the art would have been motivated to use the teachings of Campbell *et al.*, Telford *et al.* and Dominko *et al.* because at the time of the claimed invention they represented the latest and best conditions/methods available to practice nuclear transfer techniques. There would have been a reasonable expectation of success given the state of art and the ability to perform nuclear transfer procedures at the time of the claimed invention. It is noted again that the correlation between species distance still exists, however the instant methods do result in a viable embryo. Note that obviousness does not require absolute predictability of success; for obviousness under 35 U.S.C. 103, all that is required is a reasonable expectation of success. *In re O'Farrell* 7USPQ2d 1673 (CAFC 1988).

Thus, the claimed invention, as a whole, was clearly *prima facie* obvious in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach, whose telephone number is (703) 305-3732.

If attempts to reach the examine by telephone are unsuccessful, the examiner's supervisor, Karen Hauda, can be reached on (703) 305-6608.

An inquiry of a general nature or relating to the status of the application should be directed to Kay Pinkney whose telephone number is (703) 305-3553.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Deborah Crouch

DEBORAH CROUCH
PRIMARY EXAMINER
GROUP ~~1800~~ 1630

Joseph T. Woitach